

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COSIMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|--------|-------------------------|---------------------|------------------|
| 10/663,449 | 09/16 | 5/2003 | Timothy J. Fischer | 00824Div.JAR | 2189 |
| 7590 08/02/2005 | | | | EXAMINER | |
| Judith Roesle | r, Esq. | | GITOMER, RALPH J | | |
| bioMerieux, In Patent Departn | | | ART UNIT | PAPER NUMBER | |
| 100 Rodolphe | | | 1655 | | |
| Durham, NC | 27712 | | DATE MAILED: 08/02/2005 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <u></u> | | | | | | | |
|---|--|---|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | | |
| | 10/663,449 | FISCHER ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Ralph Gitomer | 1655 | | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with t | he correspondence address | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply within the statutory minimum of thirty (30 vill apply and will expire SIX (6) MONTHS, cause the application to become ABAND | be timely filed) days will be considered timely. from the mailing date of this communication. ONED (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1)⊠ Responsive to communication(s) filed on 23 Ju | ıne 2005. | | | | | | |
| | | | | | | | |
| , | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) | re withdrawn from considerates 18,206,225,226 and 228 is/are | tion. | | | | | |
| Application Papers | • | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | epted or b) objected to by the drawing(s) be held in abeyance. ion is required if the drawing(s) i | See 37 CFR 1.85(a). s objected to. See 37 CFR 1.121(d). | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Appl rity documents have been rec u (PCT Rule 17.2(a)). | ication No ceived in this National Stage | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) ☐ Interview Sum | mary (PTO-413) | | | | | |
| 2) Notice of References Cried (PTO-032) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | Paper No(s)/M | ail Date mal Patent Application (PTO-152) | | | | | |

M

Applicant's election without traverse of Group I in the reply filed on 6/23/05 is acknowledged. In view of the preliminary amendment received 9/16/03, the following claims are considered here: 60, 63, 65, 66-69, 74, 78-79, 87, 88, 91-94, 188, 206. Claims 225, 226, 228 are withdrawn from consideration as non-elected without traverse.

The specification refers to a number of references such as Givens but does not include complete citations. A complete bibliography is required. No IDS is found in this file.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 188 and 206 are drawn to a method which is not found in the specification as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60, 63, 65, 66-69, 74, 78-79, 87, 88, 91-94, 188, 206 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Application/Control Number: 10/663,449

Art Unit: 1655

There are many instances of lack of antecedent basis in the claims. In claim 60 line 1, "the coagulation system" lacks antecedent basis. In claim 63 line 2, what the protein C is added to is not set forth. In claim 65 line 3, what the vesicles are included in is not set forth. In claim 74 line 1, "the rate" lacks antecedent basis. In claim 78(b) "triggering" is queried. In claim 87 "said fibrin polymerization profile" lacks antecedent basis. In claim 92 "said at least one parameter" lacks antecedent basis. In claim 188(i) "the second patient sample" lacks antecedent basis. In claim 188(j) "the effectiveness" and "the pharmaceutical therapy" lack antecedent basis. In claim 206(i) "the degree" lacks antecedent basis. In claim 206(j) "the efficacy" lacks antecedent basis.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because of the restriction.

Correction is required. See MPEP § 608.01(b).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tejidor (6,645,768) teaches a reagent for assessing a coagulation system.

Braun (6,321,164) teaches time dependent profiles of coagulation.

Fischer (6,743,596) is the parent patent.

Toh (WO 00/46603) teaches tem dependent coagulation profiles.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ralph Gitomer Primary Examiner Art Unit 1655

RCellome

RALPH GITOMER PRIMARY EXAMINER GROUP 1200